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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040315

Application Number: 09/777,874
Filing Date: February 07, 2001
Appellant(s): CLAUDIO, CAVAZZA

Thomas M. Cunningham
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10-08-2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

1) The 103 rejection of claims 11-18 and 20-31 over Weigand by itself is withdrawn.

2) The 103 rejection of claims 28-29 over Weigand in view of Moffett is withdrawn.

3) The 103 rejection of claims 28-30 over Hastings in view of Weigand and Burtle individually or in combination.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 11-18 and 20-31 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

3,810,994	WIEGAND	5-1974
4,268,524	CAVAZZA	5-1981
5,008,288	STRACHER	4-1991
5,030,657	BURTLE	7-1991
5,536,516	MOFFETT	7-1996
5,626,849	HASTINGS	5-1997

WEINER in "Drug Development and Industrial Pharmacy", vol. 15, # 10, pp 1523-1556, 1989.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 U.S.C. § 103

1. Claims 11-18, 20-27 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiegand (3,810,994) in view of Moffett (5,536,516).

Wiegand teaches that the anti-obesity compound can be administered along with other anti-obesity compounds (column 3). Weigand however, does not specifically teach that compound to be hydroxy citrate or that hydroxycitrate be in the form of Garcinia extract. The use of an art known anti-obese agent such as hydroxycitrate in combination with carnitine would have been obvious to one of ordinary skill in the art since Weigand advocates such a use. An artisan would be further motivated to use hydroxycitrate or hydroxycitrate containing Garcinia extract since Moffet teaches that this compound present in Garcinia, is an inhibitor of the synthesis of fat and cholesterol and is known to reduce the body weight and lower lipid accumulation (note the abstract, col. 1, line 5 et seq.).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant while agreeing that Wiegand is suggestive of use of esters of carnitine including acetylcarnitine for the treatment of obesity argues that Weigand does not teach or suggest combination of hydroxycitric acid and acetyl-L-carnitine. Appellant similarly argues that Moffett is directed to hydroxycitric acid concentrates and Moffett does not suggest acetyl-carnitine. Applicant is incorrect in stating that Weigand is directed to carnitine; Weigand on col. 2, line 42 clearly teaches acetyl-carnitine. The examiner agrees that Wiegand does not teach hydroxycitric acid; however, as pointed

above, Wiegand teaches the combination of acetyl-carnitine along with other anti-obesity compounds, but points out that one of ordinary skill in the art would be motivated to combine two components having the same effect with the expectation of obtaining at least an additive effect (see In re Kerhoven 205 USPQ 1069). With regard to synergism argued by applicant, the examiner points out that a careful examination of the data shows just an additive effect. The examiner respectfully directs the board's attention to Table 2 (submitted on January 2, 2002) for e.g., the values for hydroxycitrate at 1 g/100 g diet and 2 g/ 100 g diet in the table on page 3 of the declaration are 46.6 + 4.1 and 38.9 + 3.8 respectively, compared to the control values of 62.8+3.5: the value for acetyl carnitine at 2 g/100 g diet 60.4 + 7.1 (this value is almost the same as control): the combined value of hydroxycitrate and acetyl-carnitine as noted from this table is 31.6 +3.9. This value is the same as that observed with hydroxycitrate taking into consideration the stand deviation. This value is not even additive. Similar is the case with values reported in tables 4 and 5 on pages 4 and 5 of the declaration. Furthermore, the scope of the claims is not commensurate with the amounts recited in the tables. Appellant in response argues that the examiner has not provided an adequate scientific or mathematical basis for his conclusion, particularly in view of the T-test scores showing statistical significance also shown in the declaration. The examiner is not questioning statistical method of analysis of the data; but is questioning the interpretation of the data. The examiner is unable to determine the claimed statistical significance since it is unclear as to what they are compared to. For example a careful review of Tables 2, 4 and 5 (submitted on January 2, 2002) shows that even

controls have a $p < 0.001$. How can this be possible and how can one evaluate the statistical significance of the results. Even assuming that the values are statistically significant, a question arises as to the patentable significance of the results with such overlapping values. In summary, the examiner finds no unexpected or synergistic effect of the combination of acetyl-carnitine and hydroxy-citric acid.

2. Claims 11-18, 20-27 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (5,626,849) by itself or in view of Wiegand (3,810,994), Burtle (5,030,657) by themselves or in combination.

Hastings teaches dry formulations containing calcium salt of hydroxy citric acid, L-carnitine salt, Chromium, antioxidants and other components for weight loss (note the abstract, columns 1-5, examples and claims). Hastings teaches the composition in the form of tablets, emulsions and suspensions (col 2, lines 32-61). Although Hastings does not specifically teach that the composition is in the form of semi-solid, semi-liquids, such is inherent since Hastings teaches the mixing of the composition with a liquid and depending upon the dissolvability of the composition, one would end up with a semi-solid composition. As pointed out above, Hastings teaches the oral administration of a composition containing carnitine and hydroxy citric acid. Hastings does not teach acetyl-carnitine. It would however be obvious to an artisan to use various forms of carnitine from Hastings' teachings that "any other form of L-carnitine can be used (col. 3, lines 40-45) with the expectation of obtaining at least similar results since the active agent is carnitine.

Weigand teaches compositions containing carnitine or esters of carnitine and pantothenic acid for the treatment of obesity. The composition can be administered orally or parenterally (note the abstract, columns 2-3 and claims).

Burtle teaches compositions containing carnitine or esters of carnitine and pantothenic acid (note the abstract, column 7 and claims).

The use of various forms of carnitine such as esters instead of carnitine itself as taught by Hastings would have been obvious to one of ordinary skill in the art since the references of Burtle and Wiegand show that the esters of carnitine are known for their use in the treatment of obesity; one would expect at least similar results.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the lack of teachings of acetyl-carnitine in Hastings and the observed apparent synergistic effect with the combination. These arguments are similar to those put forth for the rejection of claims over Wiegand and Moffett and hence the same response from the examiner as above, is applicable.

3. Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (5,626,849) by itself or in view of Wiegand (3,810,994), Burtle (5,030,657) individually or in combination, further in view of applicant's statements of prior art.

Hastings, Wiegand and Burtle do not teach the addition of hydroxy citric acid in the form of a natural plant extract containing said acid. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to add the claimed

extracts which according to applicant are well known extracts containing the hydroxy citric acid (page 4 of the specification), with the expectation of obtaining at least similar effect as that observed with the hydroxy citric acid itself.

Applicant provides no specific arguments regarding this rejection and therefore, the rejection is maintained.

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings cited above by itself, or in view of Wiegand (3,810,994), Burtle (5,030,657) individually or in combination, further in view of Weiner (1989) by itself or in combination with Stracher (5,008,288).

The references of Hastings, Wiegand, Burtle do not teach the administration of the composition in liposomes as vehicles.

The use of liposomes as carriers for the composition containing carnitine would have been obvious to an artisan since Weiner teaches the advantages of liposomes as drug delivery devices (note page 1523 and 1553) and also in view of the art known use of liposomally encapsulated carnitine derivatives. Applicant has not shown any unexpected results.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the apparent observed synergistic effect with the combination. This argument has been addressed above.

5. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiegand in view of Moffett: OR Hastings (5,626,849) by itself or in view of

Wiegand (3,810,994), Burtle (5,030,657) individually or in combination, both as set forth above, further in view of Cavazza (4,268,524).

Weigand, Burtle, Moffett and Hastings do not explicitly teach that the carnitine derivatives lower cholesterol and triglyceride levels.

Cavazza teaches that acetylcarnitine lowers both cholesterol and triglyceride levels (note the entire patent). It would have been obvious to one of ordinary skill in the art that the compositions taught by Wiegand, Burtle, Moffett and Hastings would lower cholesterol and triglycerides and therefore could be used for hypertriglyceridaemia and hypercholestolaemia.

Applicant's arguments have been fully considered, but are not found to be persuasive. Appellant argues that Cavazza is generally directed to a method of using acylcarnitine to increase the levels of high-density lipoproteins and that while Table 4 of Cavazza indicates the effects of acylcarnitine on serum lipids, it does not disclose or suggest the synergistic properties of the combination of acetyl-L-carnitine and HCA. Appellant's arguments once again are based on apparent synergistic values seen in Tables 4 and 5 of the declaration filed on January 2, 2002. These have been addressed above.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Art Unit 1615

GSK
March 16, 2004

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